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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,061	01/17/2001	Melanie M. Sohocki	25630/16UTL	7715

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	**PAPER NUMBER**
1639	
MAIL DATE	**DELIVERY MODE**
05/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/765,061	SOHOCKI ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-8,14-20,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13,21-24 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Application 09765061, (20030022165 A1): Claims 1-27 are pending. Claims 1-8, 14-20, 25 and 26 are withdrawn from consideration. Claims 9-13, 21-24 and 27 are examined.

Election/Restrictions

2. This application contains claims 1-8, 14-20, 25 and 26 drawn to an invention nonelected with traverse in the Paper entered 7/6/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application, 09/765,061, was filed 1/17/2001.

4. The examiner respectfully submits that the application does not satisfy the requirements for 35 U.S.C. 119(e) benefit.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the

reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional

information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Benefit to Serial No. 60/331362

5. The examiner respectfully notes that the image file wrapper shows a preliminary amendment, filed 5/2/2002, which amends the Specification at p. 1, lines 5-7, from stating "set bearing Express Mail Label EL 389 348 319 US to the United States Patent and Trademark Office" to --Serial No. 60/331362 filed--. The effect of this proposed amendment would be to change the specification, as filed, to clearly claim of benefit of Serial No. 60/331362, filed 1/4/2001.

However, a Notice of Non-Compliant Amendment, mailed 7/1/2002, found that a clean version of the entire page showing changes, had not been furnished, as required.

Because applicant has not provided the required clean version, the examiner does not consider that a perfected claim to benefit of provisional application Serial No. 60/33162, filed Jan. 4, 2001, has been made. Therefore, benefit of Serial No. 60/331362, filed Jan. 4, 2001, is *not* granted to the instant application.

The examiner respectfully acknowledges the Decision on Petition, mailed 3/12/2007, granting conversion of Serial No. 09/754,842, filed 1/4/2001, to 60/331,362. The examiner respectfully assumes that the disclosure of the specifications of Serial No. 09/754,842 and the document "set bearing Express Mail Label EL 389 348 319 US", formerly known as Serial No. 60/331362, filed 1/4/2001, to be identical. If applicant disagrees with this assumption, applicant should so state on the record.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

This objection to the oath/declaration is maintained because a new oath has not been filed.

Specification

7. Applicants disclose nucleotide sequences in the drawings, particularly Figures 1

and 9, that must be identified by a SEQ ID number, pursuant to 37 CFR 1.821(d), which states: "Where the description or claims of a patent application discuss a sequence listing that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." The identification of the sequences by SEQ ID numbers may be in the Brief Description of the Figures; or in the drawings themselves.

Because the aforementioned sequences are still not identified by SEQ ID No.s, the objection is maintained.

Withdrawn Claim Objections/Rejections

8. The following claim objections/rejections are withdrawn in view of applicant's arguments and amendments to the claims:

9. Claims 9-13 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for lack of written description.

10. Claims 9-13, 21-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 9-13, 21-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sohocki et al., Nature Genetics, Jan. 1, 2000, Vol. 24, pp. 79-83.

This rejection is maintained for the reasons of record, as set forth in the previous Office action. That rejection is copied below for the convenience of the reader.

The claims, (as in claim 9 et seq.), are drawn to a method to determine if an animal has a retinal disease or has a propensity to pass a retinal disease to offspring, comprising the steps of: (A) extracting polynucleotide from a cell or sample; (B) determining if the polynucleotide contains a mutation in an AIPLI encoding or regulating region; and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and variations thereof.

Also, the claims, (as in claim 21 et seq.), are drawn to methods for determining the presence of an APLI mutant in a patient sample, which comprises: (A) isolating polynucleotide extracted from the patient sample; (B) hybridizing a detectably labeled oligonucleotide to the polynucleotide isolated in step (b), the oligonucleotide having at its 3' end at least 15 nucleotides complementary to a wild type polynucleotide sequence having at least one mutation; (C) attempting to extend the oligonucleotide at its 3'-end; (D) ascertaining the presence or absence of a detectably labeled extended oligonucleotide; and (E) correlating the presence or absence of a detectably labeled extended oligonucleotide in step (e) with the presence or absence of a AIPL1 Trp278X mutation; and variations thereof.

Also, the claims, (as in claim 27), are drawn to a method to determine if a cell or sample has an APL1 mutation comprising: (A) extracting polynucleotide from a cell; (B) amplifying polynucleotides which encode APL1; and (C) determining if the polynucleotide contains a Trp278X mutation; (D) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and variations thereof.

Sohocki et al., Nature Genetics, Jan. 1, 2000, Vol. 24, pp. 79-83, throughout the publication, and abstract disclose methods to determine if an animal has a retinal disease or has a propensity to pass a retinal disease to offspring, (see, e.g., Fig. 5), comprising the steps of: (A) extracting polynucleotide from a cell or sample, (e.g., p. 81, para 1); (B) determining if the polynucleotide contains a mutation in an AIPLI encoding or regulating region, (see e.g., Fig. 2, demonstrating mutant sequences, and p. 80, teaching elected mutation Trp278X); and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring, (see, e.g., Fig. 5); and as in instant claims 9-13.

Sohocki et al., throughout the publication and in the abstract, disclose methods for determining the presence of an APLI mutant in a patient sample, including members of a Pakistani family, LCA4 family, which comprises: (A) isolating polynucleotide extracted from the patient sample; (B) hybridizing a detectably labeled oligonucleotide to the polynucleotide isolated, (see, e.g., Fig. 1), the oligonucleotide having at its 3' end at least 15 nucleotides complementary to a wild type polynucleotide sequence having at least one mutation, (see, e.g., Figure 2); (C) attempting to extend the oligonucleotide at its 3'-end, (see, e.g., Fig. 1, Methods Section, p. 81, para 4-5, p. 82, para 2, p. 83, para 2); (D) ascertaining the presence or absence of a detectably labeled extended oligonucleotide; and (E) correlating the presence or absence

of a detectably labeled extended oligonucleotide with the presence or absence of a AIPL1 Trp278X mutation (see p. 80, para 1-6, Fig. 5); as in instant claims 21-24. Sohocki et al., in the abstract, teach taking a patient sample prior to isolation. Sohocki et al., at Fig. 1, and p. 81, para 6, teach amplification, hybridization, and fluorescence *in situ* hybridization (fluorochrome label), northern blot (radioisotope label), and digoxygenin *in situ* hybridization (enzyme label); as in instant claims 21-24.

Sohocki et al, throughout the publication, disclose method to determine if a cell or sample has an APL1 mutation comprising: (A) extracting polynucleotide from a cell; (B) amplifying polynucleotides which encode APL1; and (C) determining if the polynucleotide contains a Trp278X mutation; (D) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; as in instant claim 27.

Response to Arguments

Applicant argues that the abstract (publication?) did not include the sequence information, which did not become available some time after 1/4/2000. Therefore, the cited reference is not "proper 102(b) reference as it is the inventors work and the a patent application was filed prior to the publication of an enabling disclosure of the subject matter of current claims", (Reply at p. 13).

Applicant's arguments, entered 3/12/2007, have been fully considered but they are not persuasive. Firstly, the examiner respectfully submits that the Sohocki et al. publication has a publication date, Jan. 1, 2000, that is more than one year even before the filing date of the alleged "priority document", provisional No. 60/331362, filed 1/4/2001, (see also, *supra*, para 4, finding applicant's benefit claim insufficient).

Secondly, Sohocki et al., e.g., at pp. 80, para 6, 82, Fig. 5, discloses the required sequence information. If applicant's representative is arguing the Sohocki et al. (2000), is inaccurate, applicant should provide objective evidence attesting thereto, for example in the form of a declaration pursuant to 37 CFR 1.132. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir

1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). MPEP 2145.

13. Claims 9, 12, 13 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Damji, et al., American Journal of Human Genetics, Oct. 2000, Vol. 67, No. 4 Supplement 2, pp. 382, Abstract 2142.

This rejection is maintained for the reasons of record, as set forth in the previous Office action. That rejection is copied below for the convenience of the reader.

Damji, et al., throughout the abstract, teach a method to determine if a human patient, (understood here to encompass broadly "an animal", as in the claim) has a retinal disease or has a propensity to pass a retinal disease to offspring, comprising the steps of: (A) extracting polynucleotide from a cell or sample; (B) determining if the polynucleotide contains a mutation in an AIPL1 encoding or regulating region; and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and wherein the determining is done via sequencing, (as in claim 12); and wherein the mutation is Trp278X, as in claim 13.

Response to Arguments

Applicant argues that "[a]pplicants' 2000 publication clearly antedate this reference [Damji et al.] and as the provisional application to which this application claims priority was filed less than one year after an enabling publication", (Reply at p. 14).

Applicant's arguments, entered 3/12/2007, have been fully considered but they are not persuasive. The examiner respectfully submits that there is no such thing as a "2000 publication" by the applicant, because the inventive entity of Damji et al., is not

the same as the inventive entity of the instant application. The Damji et al. publication has a publication date, Oct., 2000, which is before even before the filing date of the alleged "priority document", provisional No. 60/331362, filed 1/4/2001, (see also, *supra*, para 4, finding applicant's benefit claim insufficient). The examiner respectfully submits that applicant's arguments are not sufficient to overcome the instant anticipatory rejection, regardless of the granting of applicant's benefit claim.

Conclusion

14. Claims 9-13, 21-24 and 27 are rejected.

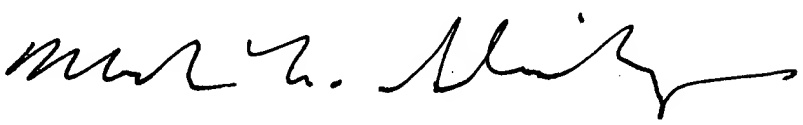
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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